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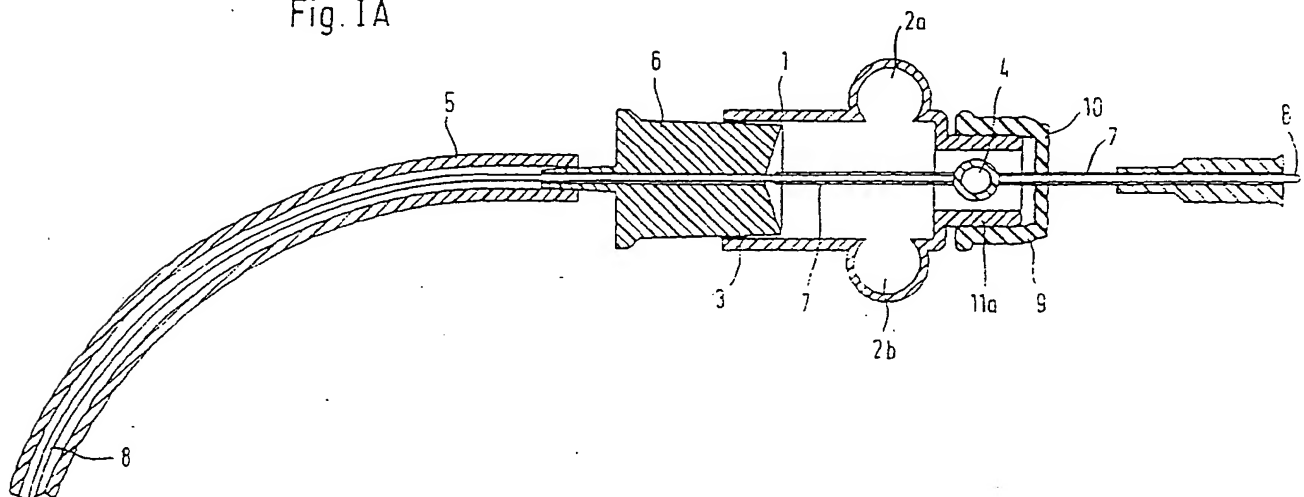
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(54) Adapter for continuous intratracheal instillation of a liquid medium

(57) The adapter consists of a hollow core piece 1 comprising means for receiving a tracheal tube 5 via lug-like member 6, arms 2a, 2b for the connection of respiratory tubes for breathing in and out and an extension 11a positioned axially opposite to the tube receiving means for the receipt of means enabling continuous instillation of e.g. lung surfactant, the extension being sealed off by a rubber cap 9 having a membrane 10 which is self-sealing after perforation and which is capable of receiving a guide cannula 7 for a catheter 8. A connector 4 may be provided for connecting the core piece to a respiratory pressure measuring apparatus.

Fig. 1A



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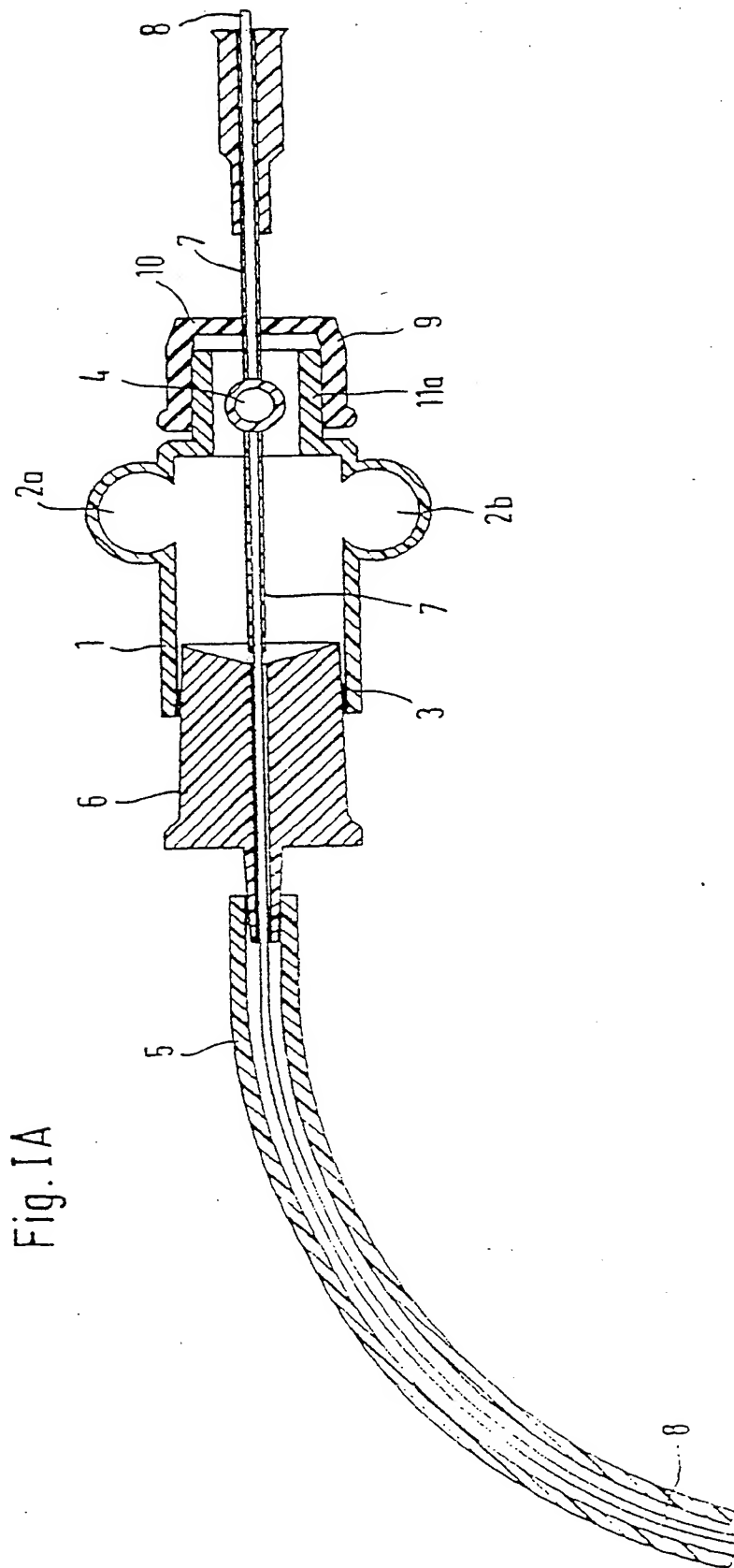
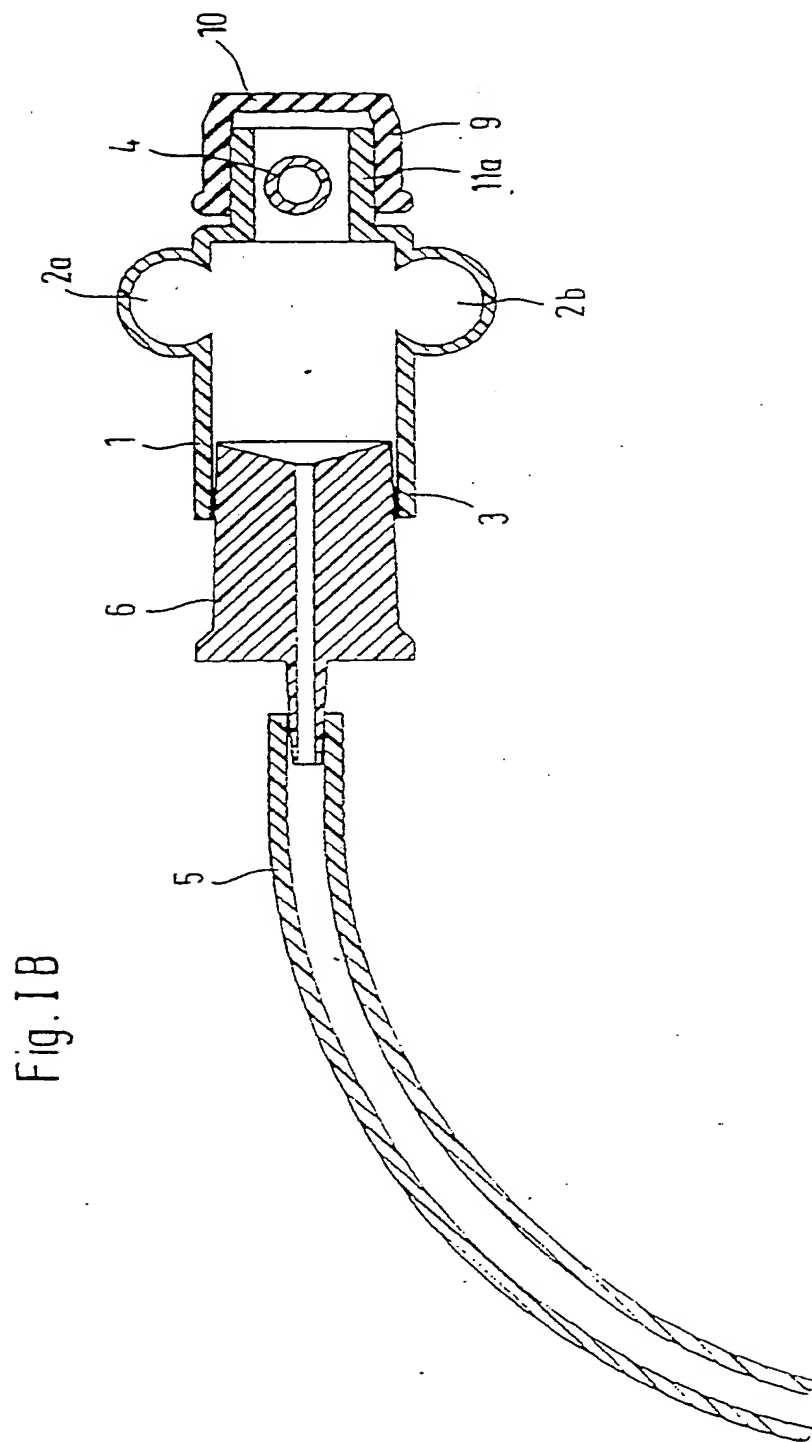


Fig. 1A



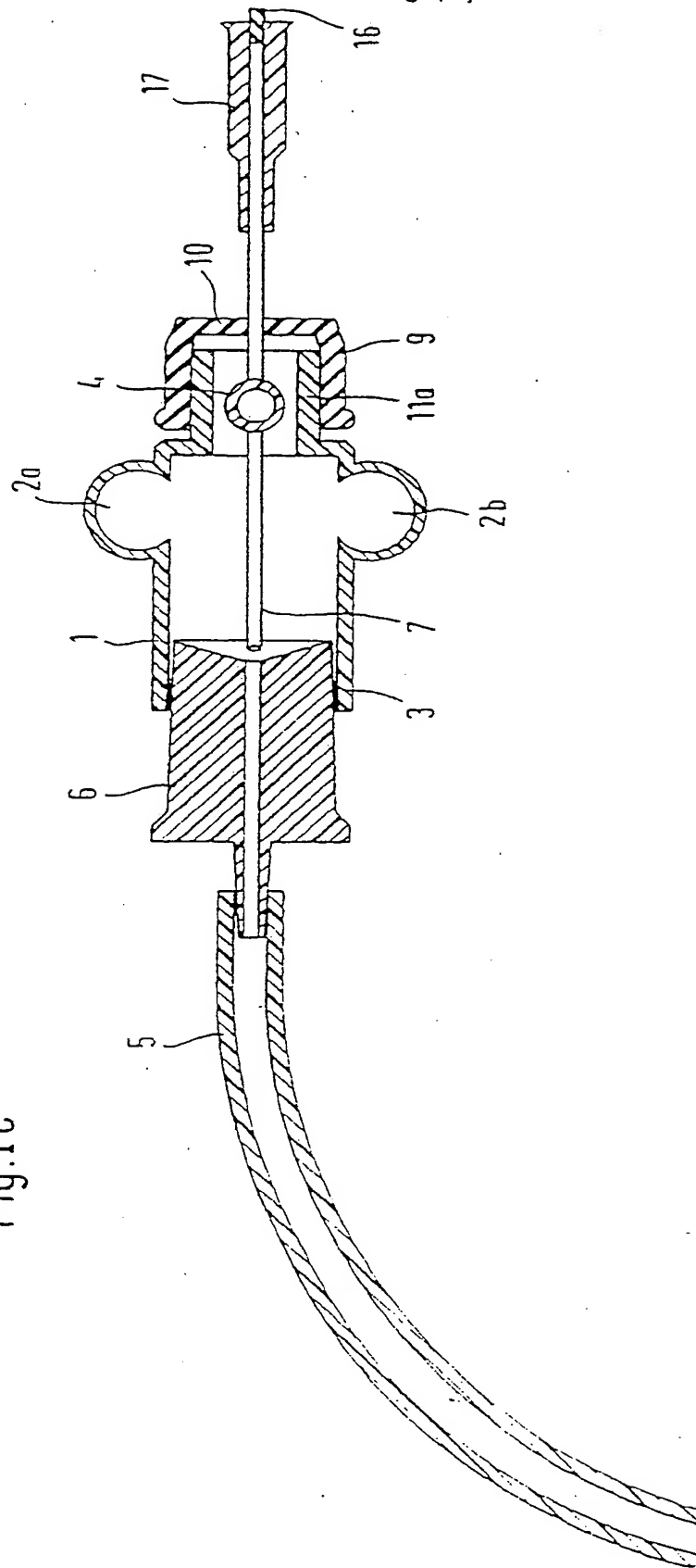
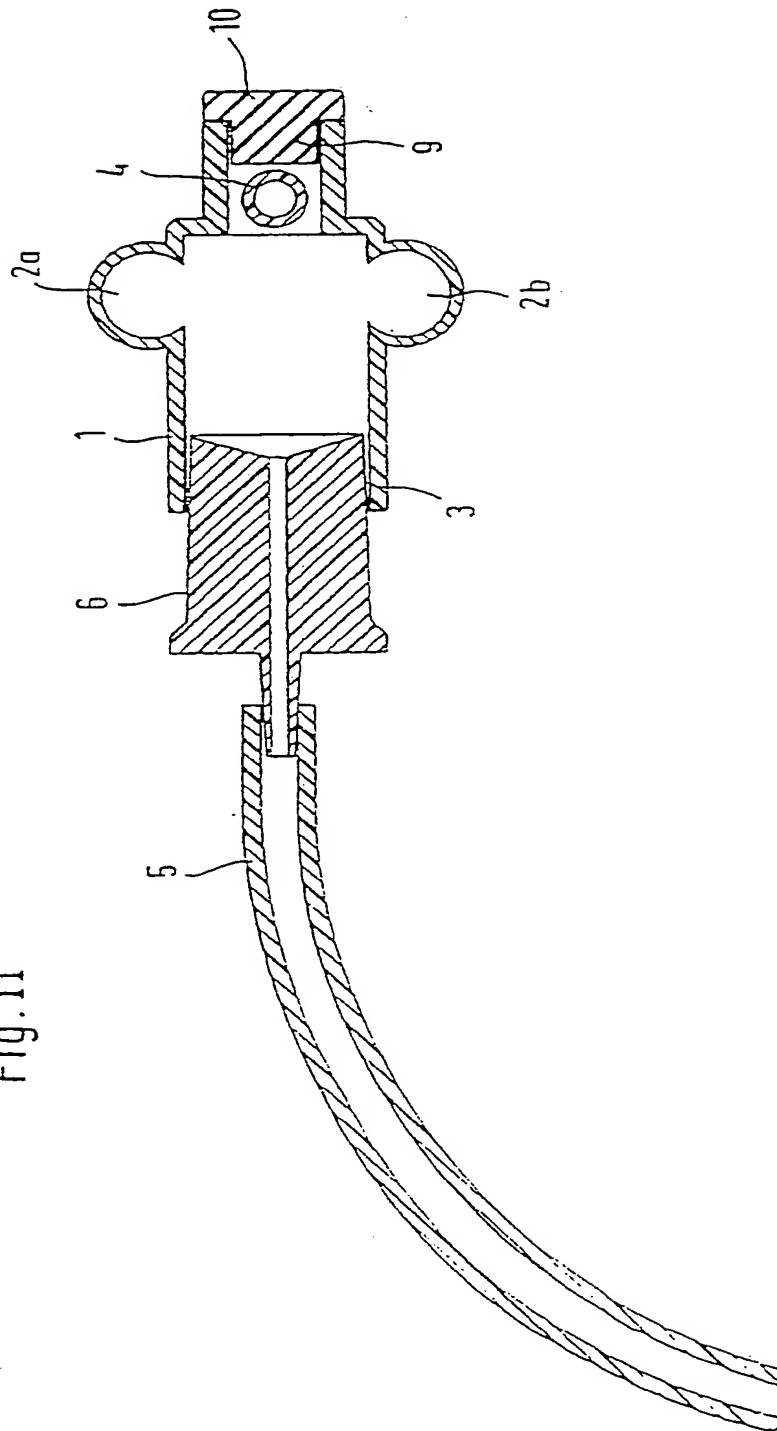


Fig. 1C

Fig. II



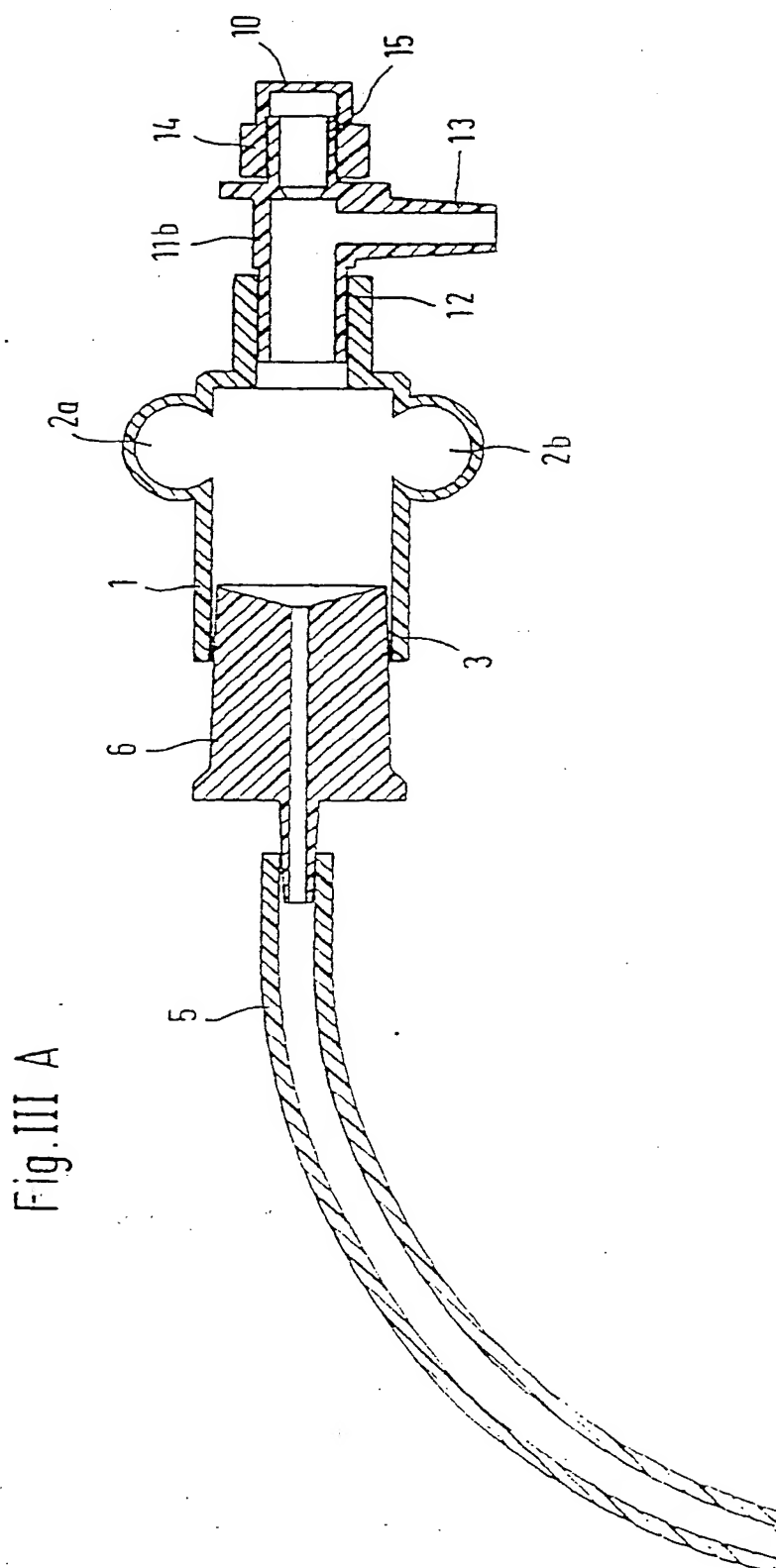
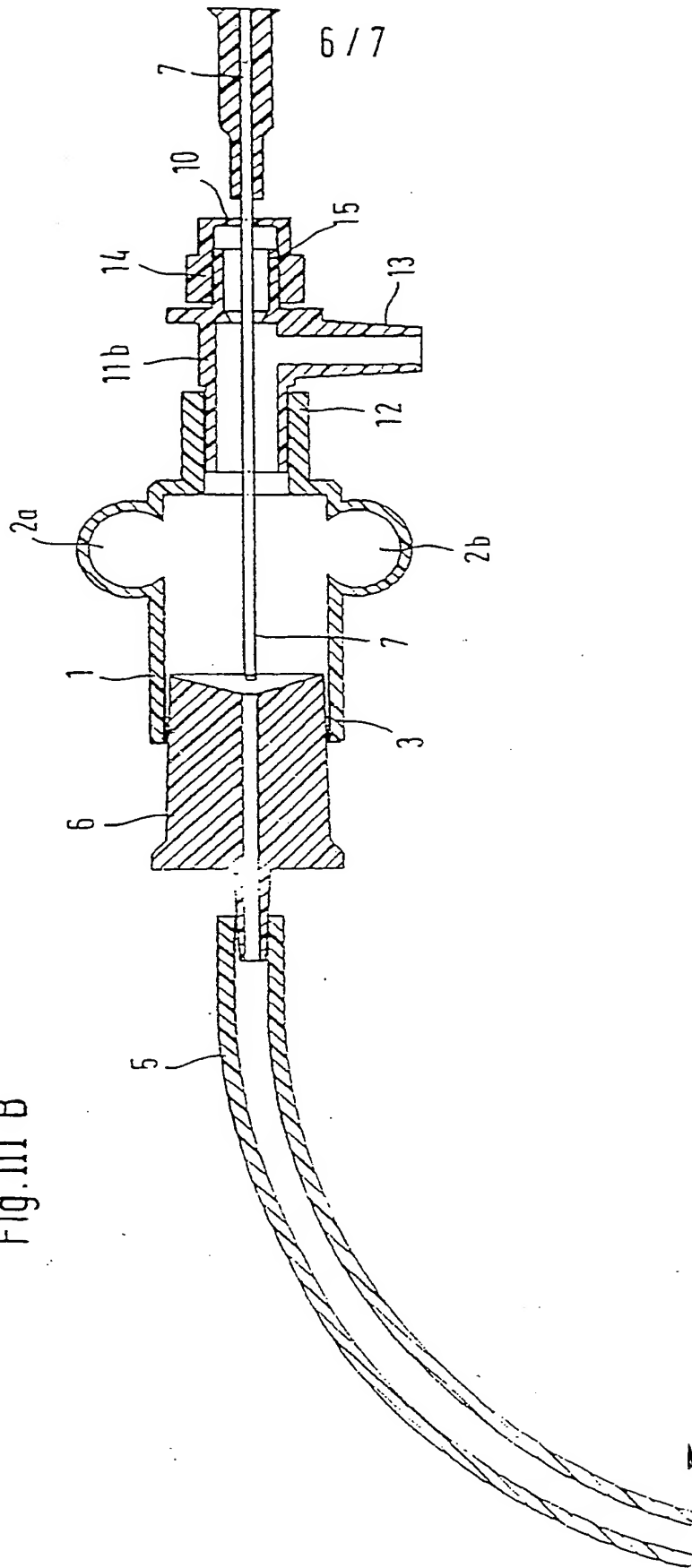
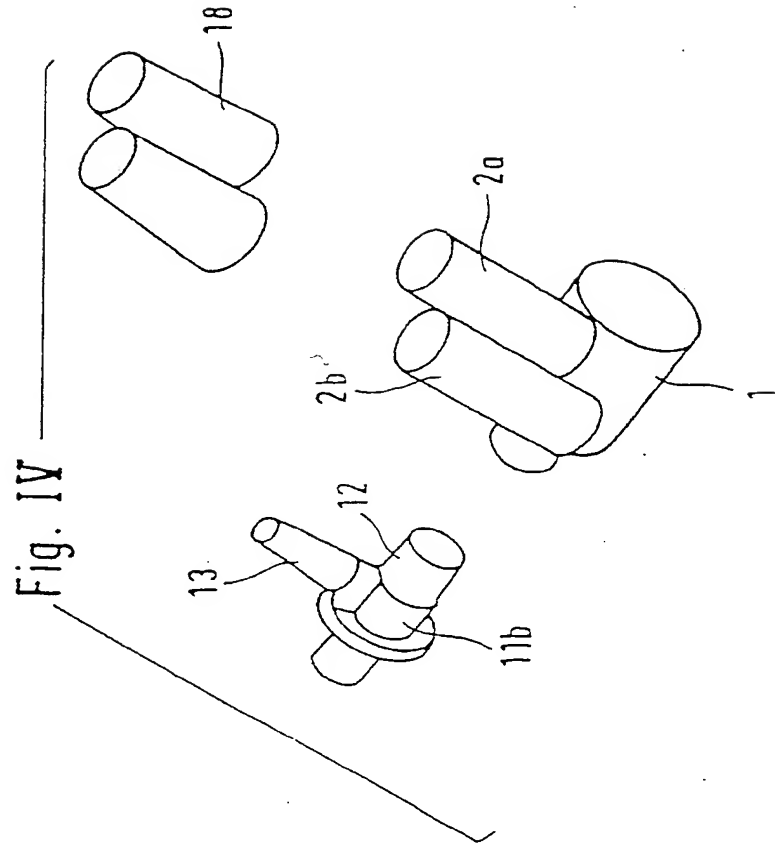


Fig. III B





Adapter for the continuous intratracheal
instillation of a liquid medium

5

This invention relates to an adapter for the continuous intratracheal instillation of a liquid medium, e.g. lung surfactant.

Up till now, lung surfactant has been administered
10 to the intubated patient as a bolus through a catheter inserted in the respiratory tract (tracheal tube). To do this, the patient had to be briefly disconnected from the respirator in order that the catheter could be inserted into the tracheal tube, and this operation
15 meant that there was a definite risk of interrupting the mechanical respiration. This brief interruption in respiration constitutes a severe problem for the patient which is reflected, for example, in a sharp increase in blood pressure. Situations of this kind would be
20 particularly threatening in premature babies as fluctuations in blood pressure play a major role in the occurrence of cerebral bleeding. However, in individual cases, the administration of a bolus may also lead to a brief shifting of the respiratory tract as a result of
25 the quantity of liquid given, with a rise in respiratory resistance, of a limited duration, and consequently a drop in the oxygen tension and a rise in the CO_2 -tension in the blood, all of which makes for a serious stress situation for the patient.

30 According to the present invention there is provided an adapter for the continuous, intratracheal instillation of a liquid medium into the lower end of the trachea, consisting of a hollow core piece comprising, means for receiving a tracheal tube,
35 connecting means projecting laterally from the core piece for connecting the core piece with respiratory tubes for breathing out and in through the tracheal

tube, and means for enabling instillation being provided axially positioned relative to the tracheal tube receiving means, said instillation enabling means being sealed off on the outside with a cap or stopper the surface of which consists of a material which reseals itself after perforation and, in the ready-to-use condition of the adapter, a guide cannula may be inserted in close-fitting manner in the centre of the stopper or cap, the guide cannula terminating short of the tracheal tube, and a catheter may be inserted tightly against the walls of the guide cannula, with its end pushed forward to the tip of the tracheal tube.

By means of this arrangement the continuous administration of surfactant is enabled without interrupting respiration.

In one embodiment there is provided an adapter for the intratracheal continuous instillation of, for example, lung surfactant, this adapter consisting of a core Y-piece having five attachments, namely

- a. one attachment (according to the International Standard: internal diameter 15 mm) for connecting the tracheal tube,
- b. two attachments in the form of arms for connecting the two respiratory tubes for breathing in and out,
- c. one connector for attaching the core piece to the respiratory pressure measuring equipment and
- d. one connector for receiving a cannula for the introduction of the catheter, this connection being located axially opposite the connector for the tracheal tube; the connector for the introduction of the guide cannula for the catheter is provided with a cap or stopper consisting of a material which seals itself after perforation, e.g. a rubber

membrane which is pierced before the start of
instillation with a point, e.g. a Teflon cannula
for insertion in a vein. After the point (mandrel)
has been removed the vein cannula is kept as a
5 guide cannula and pushed into the Y-piece up to the
start of the respiration tube.

The guide cannula may be closed off at its end
projecting from this connector by means of a Luer
10 stopper or a cap; after this closure has been removed, a
measured section of a catheter, the outer diameter of
which is less than the inner diameter of the guide
cannula, is pushed through the latter until it reaches
the tip of the tracheal tube. The surfactant
15 preparation is continuously instilled into the lower end
of the air tube through this catheter and from there is
distributed into both lungs whilst the mechanically
controlled respiration is maintained. After the end of
instillation the catheter is removed from the guide
20 cannula and the guide cannula is closed off again with a
stopper or cap at its outer end, as required, or is also
removed.

During the instillation of the surfactant the
patient continues to be ventilated continuously and
25 ventilation must continue to be monitored.

The core piece may be provided with means for
attaching a connecting tube to a respiratory pressure
measuring apparatus, or alternatively a pressure
measuring adapter may be connected between the core
30 piece and the measuring apparatus.

In a particular embodiment of the invention, the
pressure measuring adapter is connected in a plug-like
manner to the core piece and may extend axially with
respect to the attachment for receiving the top end of
35 the tracheal tube. The pressure measuring adapter may
have a conical member which is received within a
corresponding conical member on the core piece. The

tracheal tube receiving means may similarly comprise an attachment that can be connected in pressure-tight manner to the tracheal tube and is connected to the core piece in a plug-like manner. The pressure measuring adapter may comprise an attachment for mounting a connecting tube leading to the respiratory pressure measuring apparatus, and this attachment preferably runs in the same direction as the attachments for connecting the respiratory tubes. The open end of this adapter located opposite the core piece is so constructed that either a stopper, e.g. a rubber stopper, having a membrane which self-seals after perforation can be inserted therein or a cap as described above with a membrane which self-seals after perforation can be pushed in.

For handling it is desirable that the connectors for breathing in and out and the attachment for pressure measurement are arranged in the same direction so that there are no kinks in the tubes, in view of the smallness of the equipment. The particular embodiment described here, with the separate part with connectors for the respiratory pressure measuring apparatus and the cap or stopper, has the advantage that the bronchial secretions can rapidly be sucked out before the start of instillation, by the removal of this pressure measuring adapter, by means of a suction catheter inserted in the opening thus provided, and then, after the suction catheter has been removed, the adapter can be replaced in pressure-tight manner and the operations described above required for the instillation process can be carried out.

The rubber cap protects the interior of the Y-shaped core piece from contamination and prevents the respiratory system from leaking.

The catheter is loaded by hand, e.g. using a syringe, with the material to be infused, the material which is to be instilled passing into the lower end of

the trachea at the speed at which the plunger of the syringe is operated.

In another embodiment the guide cannula is incorporated in this attachment in a fixed and pressure-tight manner; the outer part of the guide cannula is
5 formed so that it can be closed off when the apparatus is not in use.

The process of instillation proceeds according to the following criteria:

10

1. the patient is lying on his back with his head straight.

2. The patient is subjected to endotracheal suction.

15

3. The instillation adapter is prepared as described; the syringe containing the liquid active substance and a pre-marked catheter are kept in readiness,

20

4. the pre-marked catheter is introduced through the guide cannula into the tracheal tube as far as the mark,

25

5. instillation is carried out by hand in 0.1 to 0.2 ml stages every 1 to 2 minutes depending on the clinical conditions of the patient.

6. After instillation has ended the catheter is removed followed later by the guide cannula.

30

Some embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, in which:-

Fig. 1A is a cross-section through a first
35 embodiment;

Fig. 1B shows the embodiment of Fig. 1A in an alternate condition;

Fig. IC shows the embodiment of Fig. IC in an alternate condition;

Fig. II shows a modification of the embodiment of Fig. IB;

5 Figs. IIIA and IIIB illustrate the embodiment of Figs. IA-C modified by the addition of an extension tube thereto; and

Fig IV is a perspective view of one embodiment.

Figure IA shows a cross-section through a core
10 piece 1, in the form of a Y-piece with arms 2a,2b, with the tracheal tube 5 attached to an attachment formed on a plug-like member 6 in a pressure-tight manner, the plug-like member 6 being received in the core piece 1. The core piece has a connector 4 for connecting to a
15 respiratory pressure measuring apparatus. The guide cannula 7 has a catheter 8 inserted therein (e.g. a umbilical catheter) and is shown in the operational position. Figure IB shows the same piece of equipment with the umbilical catheter and cannula removed in the
20 resting position, whilst a rubber cap 9 with a membrane 10 which self-seals after perforation closes off the Y-piece 1 in pressure-tight manner in the axial, opposite extension 11a to the attachment 3 which receives plug-like member 6 for the tracheal tube 5. Figure IC shows
25 a cross-section through the same apparatus after removal of the umbilical catheter but without removal of the cannula. Instead, the guide cannula is closed off with a stopper 16.

Figure II is largely identical to Figure IB;
30 instead of a rubber cap it has a rubber stopper 9 which has a membrane 10 which self-seals after perforation.

Figures IIIA and IIIB show a cross-section through the core piece with a pressure measuring adapter in the form of an extension tube 11b attached to the fifth
35 attachment 11a in the core piece, as an alternative to connector 4 of the first embodiment. This extension tube, which is designed to be removable, having an

attachment 13 for joining a connecting tube leading to
respiratory pressure measuring apparatus and at its
free, non-insertable end is constructed so that either a
stopper, e.g. a rubber stopper, with a membrane which
5 self-seals after perforation can be inserted therein in
pressure-tight manner or a cap 14, e.g. a rubber cap,
having a connecting member 15 with a similar membrane
can be put in there. Figure IV shows a perspective view
of a core piece 1 with the arms projecting in the same
10 direction away from the core piece.

Claims

1. An adapter for the continuous, intratracheal
instillation of a liquid medium into the lower end of
5 the trachea, consisting of a hollow core piece
comprising, means for receiving a tracheal tube,
connecting means projecting laterally from the core
piece for connecting the core piece with respiratory
tubes for breathing out and in through the tracheal
10 tube, and means for enabling instillation being provided
axially positioned relative to the tracheal tube
receiving means, said instillation enabling means being
sealed off on the outside with a cap or stopper the
surface of which consists of a material which reseals
15 itself after perforation and, in the ready-to-use
condition of the adapter, a guide cannula may be
inserted in close-fitting manner in the centre of the
stopper or cap, the guide cannula terminating short of
the tracheal tube, and a catheter may be inserted
20 tightly against the walls of the guide cannula, with its
end pushed forward to the tip of the tracheal tube.

2. An adapter as claimed in claim 1 wherein means are
provided for connecting the core piece to respiratory
25 pressure measuring apparatus.

3. An adapter according to claim 2, wherein a tubular
pressure measuring adapter is connected to the core
piece in pressure-tight manner, the pressure measuring
30 adapter having a pressure measuring connector and,
axially with respect to the core piece, a connecting
member with a closure cap or stopper, the upper parts of
which consist of a membrane of a material which self-
seals after perforation, and in the ready-to-use
35 condition of the adapter, the guide cannula is inserted
in close-fitting manner through the centre of the
membrane.

4. An adapter according to claims 1, 2 or 3, wherein the tracheal tube receiving means comprises an attachment that can be connected in pressure-tight manner to the tracheal tube and is connected to the core piece in a plug-like manner.
- 5
5. An adapter according to claim 3 wherein the pressure measuring adapter is connected to the core piece in a plug-like manner.
- 10
6. An adapter according to any preceding claim wherein in use the guide cannula is installed in the core piece in fixed and pressure-tight manner.
- 15
7. An adapter according to any preceding claim wherein the guide cannula can be closed off, at its end projecting from the adapter, with a cap or a Luer stopper and the inner diameter of the guide cannula is only slightly greater than the outer diameter of the catheter.
- 20
8. An adapter for the continuous intratracheal instillation of a liquid medium into the lower end of the trachea substantially as hereinbefore described with reference to the accompanying drawings.
- 25

Patents Act 1977

**Examiner's report to the Comptroller under
Section 17 (The Search Report)**

- 10 -

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Relevant Technical fields

(i) UK Cl (Edition K) A5R (RGE, RGM)

(ii) Int Cl (Edition 5) A61M

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Search Examiner

L V THOMAS

Date of Search

30 NOVEMBER 1992

Documents considered relevant following a search in respect of claims 1-8

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	US 4416273 (GRIMES) See lines 30-52 column 2, line 63 column 2 - line 7 column 3 and lines 31-57 column 3	1, 4, 6

SF2(p)

MS - doc99\fil000220

Category	Identity of document and relevant passages	Relevant to claim(s).

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